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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,315

Applicant(s)

MUNRO ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-15,17-20,24-38,40-43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-15,17-20,24-38,40-43 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Continued Examination and Amendments filed April 19, 2005 is acknowledged.

Claims 1-5, 9-15, 17-20, 24-38, 40-43 and 45 are pending in this application.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-15, 17-20, 24-38, 40-43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is directed to a process of coating a perforated substrate wherein step (i) comprises forming a layer of a liquid pregel mixture, comprising one or more monomers, on a web coated with a coating having a surface energy less than the surface energy of the liquid pregel mixture wherein the web comprises paper, polyester, polyolefin or any combination thereof **and/or** the coating of the web comprises silicone, polyethylene, polyvinyl fluoride, PTFE, or any mixture or combination thereof. The recitation of "and/or" is confusing since the claim requires a web however the use of "and/or" provides that the liquid pregel can be formed on a web or a coating of silicone, polyethylene, polyvinyl fluoride, PTFE. Is applicant attempting

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to claim a web **optionally** coated with of silicone, polyethylene, and polyvinyl fluoride, PTFE.

Further clarification is requested.

Claim Objections

Claim 28 is objected to under 37 CFR 1.75(c); as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 28 is directed to the process wherein the web is selected from paper, polyester, polyolefin, or combinations thereof. However, the parent claim 1 requires the same limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 38, 40-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheong (5,352,508).

Cheong discloses a net wound dressing wherein a hydrophilic resin is coated on a substrate without occlusion (abstract). At least 90% apertures of the net substrate are unoccluded. See column 3, lines 13-15. The resin is a polymerized hydrogel or crosslinked polyurethane resin (column 3). Suitable substrates are woven and non-woven materials such as polyamide, polypropylene, cotton, rayon, or wool (col. 5, lines 1-3). The amount of resin coated on the substrate is 25-300 g/m². The resin is applied to coating rollers and coated on to the substrate,

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which then undergoes heating to cure the resin (col. 5, lines 20-25 and example 5). In example 1, the reference teaches coating one side of the substrate. Cheong teaches using a release sheet to protect the hydrogel. See example 5 and column 5, lines 50-60.)

It is noted that the rejected product claims depend on process claims, however it should be noted that even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, if the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). See MPEP section 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-5, 9-10, 13-15, 17-20, 22, 24-31, 38, 40-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0567704 in view of Lauchenauer et al (4,705,584) further view of Cheong (5,352,508).

EP teaches a hydrogel gauze for wound dressing purposes. See abstract. EP teaches placing uncured hydrogel material (monomers) onto an absorbent layer in an amount sufficient to impregnate the interstices therein. The process utilizes two release sheets (22 and 24) wherein the substrate and the uncured hydrogel material is placed in between the two release sheets. A pair of rollers compress the release sheets so that the uncured hydrogel material is spread evenly onto the substrate. The sandwiched material is then cured to form a hydrated hydrogel material. The release sheets are removed and the dressing is dehydrated to provide a dehydrated hydrogel gauze. See column 6 and Figure 2. The absorbent material is selected from fabrics, natural fibers, synthetic fibers, cellulose derivatives, etc. See column 5, lines 50-56. The preferred hydrogel material preferably contains 0-90% of a polyhydric alcohol (plasticizer), about 6-60% of an aliphatic diisocyanate terminated prepolymer, 4-40% of polyethylene oxide based polyamine, and water to balance. See column 8.

EP does not teach the material of the release sheets.

Lauchenauer application of polymeric materials to the surface of a substrate. The process comprises i) applying a layer of polymeric material to a sheet material capable of acting as a release sheet; (ii) contacting the said polymeric material with the surface of the substrate to which the said polymeric materials is to be applied; (iii) applying heat and pressure sufficient to effect adhesion of said polymeric material to said substrate; and (iv) peeling the release sheet from said polymeric material. See column 1, lines 55-65. The release sheet is a non-porous

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surface and Lauchenauer teaches the preference of paper that is coated with agents to produce a low adhesion surface as the release sheet. See column 4, lines 5-10. Further polyester films are also taught as the release sheet. The release sheet is reusable and may be used in the form of a continuous belt. Substrates to be coated include knitted fabric such as cotton. See examples.

Cheong discloses a net wound dressing wherein a hydrophilic resin is coated on a substrate without occlusion (abstract). At least 90% apertures of the net substrate are unoccluded. See column 3, lines 13-15. The resin is a polymerized hydrogel or crosslinked polyurethane resin (column 3). Suitable substrates are woven and non-woven materials such as polyamide, polypropylene, cotton, rayon, or wool (col. 5, lines 1-3). The resin is applied to coating rollers and coated on to the substrate, which then undergoes heating to cure the resin (col. 5, lines 20-25 and example 5). In example 1, the reference teaches coating one side of the substrate. Cheong teaches using a release sheet to protect the hydrogel. See example 5 and column 5, lines 50-60. Cheong teaches the amount of resin coated on the substrate is 25-300 g/m² wherein the amount is sufficient to encapsulate the substrate but not occlude the apertures. See column 5, lines 5-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Lauchenauer and utilize paper optionally coated with material that provides a low adhesion surface as the release sheets (22 and 24) in EP's process. One would have been motivated to do so since both references teach a process of coating a substrate with polymeric material. Although EP fails to specify the material of the release sheet, Lauchenauer teaches the general state of the art of transfer coating wherein it is known to utilize a release sheet with a low adhesion surface such as paper, to transfer the polymer material to the desired substrate.

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With regard to the recitation of "without substantial occlusion" it is the examiner's position since the prior art and the instant invention teaches substantially similar process steps, a similar product will be provided. Furthermore, it is the examiner's position that the amount of resin coated onto the substrate will effect the occlusion or lack of occlusion of the substrate as taught by Cheong. Cheong teaches if one desires to obtain an unoccluded dressing, the resin is provided in a sufficient amount of resin to encapsulate the substrate but not enough to occlude it. Therefore, the manipulation of the amount of resin is deemed an obvious skill to one of ordinary skill as demonstrated by Cheong.

Claims 11-12 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0567704 in view of Lauchenauer et al (4,705,584) in further view Cheong (5,352,508) in further view of Kundel (5,674,346).

As set forth above, EP teaches a hydrogel gauze. The preferred hydrogel material preferably contains 0-90% of a polyhydric alcohol (plasticizer), about 6-60% of an aliphatic diisocyanate terminated prepolymer, 4-40% of polyethylene oxide based polyamine, and water to balance. See column 8. As set forth above, Lauchenauer teaches the instant release surfaces.

The references do not teach a gel containing acrylate monomer.

Kundel teaches a hydrogel wound dressing. Kundel teaches conventional polymers such as acrylates, polyethyleneoxide, etc. are used to form the hydrogel (col. 4, lines 30-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the instant references and substitute EP's hydrogel with the instant acrylate monomers. One would have been motivated to do so since Kundel teaches the conventional polymers used for making hydrogels in wound dressing compositions are

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acrylate based polymers and polyethylene oxide based polymers. Therefore, it is deemed obvious to use substitute one conventional gel material with another with the expectation of similar results since the prior art teaches the equivalency of the materials.

Claims 1-5, 9-10, 15, 17-20, 22, 24-31, 38, 40-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42985 by itself or in view of Bogusiewicz (5427096).

WO discloses a wound dressing and the method of making it. The method includes placing a gel mixture of polymers on a thin plastic film (8) (equivalent to claimed "web") and a polyurethane foam (10) (equivalent to claimed "perforated substrate") is applied to the uncured gel mixture (9) with the aid of a roller. The substrate and the gel are placed in the oven to cure the gel mixture. The gel coating should not block the pores of the substrate, thus the gel is applied in a thickness of 0.1-1 mm and the total gel layer has thickness of 0.2-2 mm. See page 9 and Figure 3. The gel layer is a chemically cross-linked silicone gel (page 5). WO teaches the use of **hydrophilic gels** in the invention. See page 15. Note WO implicitly teaches applicant's recitation "after removal of the web" since the plastic film is placed on top of and *part of* the conveyor belt and once the dressing is cured, it is removed from the conveyor belt; thus the dressing is removed from the assembly of the gel and substrate.

WO does not specify the plastic material (8) the pregel is placed on.

Bogusiewicz teaches a water-degradable electrode. The release surface is paper, polyolefin, or polyester film and Bogusiewicz teaches a preference for plastics such as polyolefin, silicon, and polyester. See column 11, lines 30-50. The reference teaches a release liner is usually has a

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low surface energy and are known in the art. The release liner may further be coated with a release agent such as silicone or PTFE.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to look and WO's and utilize instantly claimed plastics (polyolefin and polyester). One would have been motivated to do so since the term plastic encompasses polyolefins and polyesters, which are commonly known and used in the art as seen from Bogusiewicz's disclosure. Bogusiewicz's teaches that the instantly claimed materials polyester and polyolefin are known in the art to be low surface energy plastics. Therefore, it is the examiner's position that WO's plastic film that the pregel mixture is placed on, reads on the instant low surface energy web.

Claims 1-5, 9-10, 15, 17-20, 22, 24-31, 38, 40-43, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42985 in view of Lauchenauer et al (4,705,584).

WO discloses a wound dressing and the method of making it. The method includes placing a gel mixture of polymers on a thin plastic film (8) (equivalent to claimed "web") and a foam layer (10) (equivalent to claimed "perforated substrate") is applied to the uncured gel mixture (9) with the aid of a roller. The substrate and the gel are placed in the oven to cure the gel mixture. The gel coating should not block the pores of the substrate, thus the gel is applied in a thickness of 0.1-1 mm and the total gel layer has thickness of 0.2-2 mm. See page 9 and Figure 3. The gel layer is a chemically cross-linked silicone gel (page 5). WO teaches the use of hydrophilic gels in the invention. See page 15. Note WO implicitly teaches applicant's recitation "after removal of the web" since the plastic film is placed on top of and *part of* the conveyor belt

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and once the dressing is cured, it is removed from the conveyor belt; thus the dressing is removed from the assembly of the gel and substrate.

WO does not specify the plastic material.

Lauchenauer application of polymeric materials to the surface of a substrate. The process comprises i) applying a layer of polymeric material to a sheet material capable of acting as a release sheet; (ii) contacting the said polymeric material with the surface of the substrate to which the said polymeric materials is to be applied; (iii) applying heat and pressure sufficient to effect adhesion of said polymeric material to said substrate; and (iv) peeling the release sheet from said polymeric material. See column 1, lines 55-65. The release sheet is a non-porous surface such as paper or films. Lauchenauer teaches the preference of paper that is coated with agents to produce a low adhesion surface as the release sheet. See column 4, lines 5-10. Further polyester films are also taught as the release sheet. The release sheet is reusable and may be used in the form of a continuous belt. Substrates to be coated include knitted fabric such as cotton. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Lauchenauer and utilize polyester as the plastic material of choice in WO's process. One would have been motivated to do so since Lauchenauer teaches the same transfer coating where polyester films (a known plastic) are taught as the release surface of choice and may be in the form of a conveyor belt. Therefore, Lauchenauer teaches the state of the art of transfer coating wherein it is conventional to utilize plastic release surface and specifically polyester release surfaces for transferring polymeric material onto a porous substrate.

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Claims 11-12 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42985 in view of Lauchenauer et al (4,705,584) in further view of Kundel (5,674,346).

As set forth above, WO discloses a wound dressing and the method of making it. Although WO prefers the use of a silicone gel, WO teaches the use of hydrophilic gels in the invention. See page 15. As set forth above, Lauchenauer teaches the instant release surfaces.

WO does not specify the hydrophilic gel composition, in particular a hydrogel containing acrylate monomer.

Kundel teaches a hydrogel wound dressing. Kundel teaches conventional polymers such as acrylates are used to form the hydrogels (hydrophilic gels) (col. 4, lines 30-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the instant references and use an acrylate based polymer for the hydrophilic gel in WO. One would have been motivated to do so since Kundel teaches acrylate-based polymers are conventional polymers used for making hydrogels in wound dressing. Furthermore, a skilled artisan would have been motivated to acrylate monomers with a reasonable expectation of success since WO suggests using hydrophilic gel materials in place of the silicone gels.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 9-15, 17-20, 24-38, 40-43 and 45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 11/105025. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to overlapping subject matter.

The instant invention is directed to a process of coating a perforated substrate with a hydrogel for use as a wound dressing wherein the steps comprises: a) forming a liquid pregel on a layer of web with a low surface energy, wherein the web is selected from paper, polyester, or polyolefin and is coated with silicon, PTFE, polyethylene, polyvinyl fluoride, or a mixture thereof; b) applying a perforated substrate on the pregel; c) curing the assembly of web/pregel/substrate; and d) removing the web whereby the removal provides for a substrate that has unoccluded perforations and the liquid pregel reticulates along the porous substrate. The wound dressing made from the process is claimed.

Co-pending application is directed to preparing a one-sided hydrogel coated mesh substrate for use as a wound dressing wherein the steps comprises: a) forming a liquid pregel on a layer of web with a low surface energy; b) applying a the mesh having perforations on the pregel; c) allowing the pregel to reticulate along the mesh substrate; d) curing the assembly of web/pregel/substrate; and e) removing the web whereby the removal provides for a substrate that

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has unoccluded perforations. Dependent claims are directed to a web is selected from paper, polyester, or polyolefin and is coated with silicon, PTFE, polyethylene, polyvinylfluoride, or a mixture thereof. The wound dressing made from the process is claimed.

Thus, the instant invention and co-pending application are directed to similar and overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art of Interest

US 6270792 discloses a nonstick compress with an open-mesh fabric coated with a hydrophobic elastomer, wherein the meshes are unobstructed.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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